REMARKS

Claims 1-26 are currently pending in the application, with claims 1, 4-12, 15, 16, 18, 19, 21, 24, and 25 under consideration (claims 2, 3, 13, 14, 17, 20, 22, 23, and 26 having been withdrawn by the Examiner as drawn to non-elected subject matter). Claims 1, 9, 10, 15, 18, 19, and 21 are amended by the present communication. The subject amendments are supported by the specification at, for example, p. 10, ll. 22-28 and p.13, l. 31 to p. 14, l. 3, and the claims as originally filed. No new matter is introduced by the present amendments. Applicants submit that the amendments place the claims in condition for allowance or, at a minimum, in better condition for appeal. Accordingly, entry of the present Amendment is respectfully requested. Upon entry of the Amendment, claims 1, 4-12, 15, 16, 18, 19, 21, 24, and 25 will remain pending and under consideration.

Rejections under 35 U.S.C. § 102

Claims 1, 4-12, 15-16, 18-19, 21, 24, and 25 remain rejected under 35 U.S.C. 102 (a) and (e) as being anticipated by Blumenfeld et al. (U.S. Patent No. 6,528,260; hereinafter "Blumenfeld"). Applicants traverse the rejection for at least the reasons already of record and those that follow.

The present invention is directed to methods which interpret an individual's broad-based genetic profile, wherein the profile includes the individual's genomic genotype at a preselected set of markers, wherein the markers are preselected based on association or other studies to be directly or indirectly linked with a phenotypic attribute, and predicts the probability of that individual exhibiting particular phenotype(s) from one or more preselected markers. Applicants respectfully submit that Blumenfeld does not disclose the presently claimed methods of determining the probability of exhibiting a phenotypic attribute based on an individual's genotype at a preselected set of markers, markers shown through association and other studies to be linked directly or indirectly to a certain phenotypic attribute (e.g., a particular disease state), as in claim 1. Instead, Blumenfeld provides disclosure of association studies linking a previously non-identified marker to a phenotypic attribute. The present invention is not based on identification of genetic markers per se.

The Examiner asserts that Blumenfeld teaches "a method for determining whether an individual has an enhanced probability of exhibiting a phenotypic attribute," citing several passages in Blumenfeld (Office Action at p. 3). As discussed previously, a careful review of these passages reveals that each merely describe conducting an association study, linking a known phenotype or trait with a marker which is not pre-selected. For example, col. 9, fourth paragraph merely provides background on "genetic analysis of complex traits" (e.g., linkage analysis); col. 67, third paragraph provides "methods of genotyping an individual for biallelic markers"; col. 80, last two paragraphs provides a description of "population association studies"; and col. 84 first two paragraphs provides teaching regarding the selection of a population (i.e., affected or trait positive) for examination in an association study. In short, these passages describe association studies in order to identify genes or markers associated with known phenotypes. The markers cannot be pre-selected for the purpose of determining probability of exhibiting a particular attribute because the marker has not been identified previously.

Blumenfeld shows that several approaches may be employed for such studies, for example, a candidate gene approach (Blumenfeld at col. 21, lines 14-17). This approach is based on the identification of genetic markers specifically derived from genes potentially involved in a biological pathway related to the trait of interest. Accordingly, Blumenfeld chose as candidate genes, certain genes involved in drug metabolism (Blumenfeld at col. 21, lines 21-26). Thus, Blumenfeld reports the "discovery of a set of novel DME-related biallelic markers" (Blumenfeld at col. 10, lines 34-35). For example, Blumenfeld reports an association between asthma and the bilallelic markers of the MGST-II gene (Example 3), and a further association between the side effects of treatment with the anti-asthmatic drug Zyflo and the identified biallelic markers (Example 4). Thus, the focus of the teachings of Blumenfeld is the elucidation of a gene or marker responsible for a known phenotype. The claims of the present invention do not require or envision identification of new markers-the markers are known and pre-selected for the probability study.

Further, Blumenfeld does not disclose a method of reporting information obtained from an interpretation of an individual's broad-based genetic profile to that individual (i.e., "evaluating genomic markers from an individual for zygosity at each member of a preselected set

of markers, wherein the markers are preselected based on association or other studies to be directly or indirectly linked with a phenotypic attribute"), in which the phenotypic attributes are subjected selection criteria (i.e., "applying one or more selection criteria for each of the one or more phenotypic attributes"), comparing a multivariate scoring matrix to the marker set to obtain a single risk score for each selected phenotype (i.e., "determining the probability of exhibiting a phenotypic attribute based on the marker score"), and combining with other information (e.g., "information that is relevant to the individual's probability of exhibiting a phenotypic characteristic"), and communicating the results to the individual, for example, in a report (as in claim 9).

In response to Applicants' arguments in the previous Amendment, the Examiner asserted that "claim 1 does not specifically disclose the above limitations as suggested by Applicant (i.e. deriving a probability, markers shown through association and other studies to be linked directly or indirectly)" (Office Action at p. 6). Without acquiescing to the reasoning offered by the Examiner and in order to expedite prosecution, Applicants have amended claims 1 and 9 herein to recite that the preselected set of markers are "preselected based on association or other studies to be directly or indirectly linked with a phenotypic attribute." In addition, claims 1 and 9 have been further amended to recite a step of determining the probability of exhibiting one or more phenotypic attributes. Support for these amendments may be found throughout the specification at, for example, p. 10, ll. 22-28 and p.13, l. 31 to p. 14, l. 3, and the claims as originally filed.

Based on the reasons set forth above it is respectfully submitted that the present claims clearly distinguish over Blumenfeld. Applicants' claims are not based on identification of markers which associate with a trait or attribute. Applicants provide method for assessing probabilities related to pre-selected markers. Accordingly reconsideration and withdrawal of this rejection are respectfully requested.

CONCLUSION

In view of the foregoing amendments and remarks, Applicants submit that the claims are in condition for allowance, and a notice to that effect is respectfully requested.

The Commissioner is hereby authorized to charge the total amount of $335.00 to cover the One-Month Extension of Time fee ($65.00) and the Notice of Appeal fee ($270.00) to Deposit Account No. 07-1896. Additionally, the Commissioner is authorized to charge any other fees associated with the filing submitted herewith, or credit any overpayments to Deposit Account No. 07-1896 referencing the above-identified attorney docket number. The Examiner is invited to contact Applicant's undersigned representative if there are any questions relating to this application.

Respectfully submitted,

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